Questions for August 22, 2001 NMQAAC Discussion

The following questions and answers (Q/A's) are to be discussed at the August NMQAAC meeting. Many of these Q/A's are already part of our approved guidance but are being modified to clarify them or address public comments we have received. Some of the Q/A's are new. The new Q/A's have been developed to address questions we have received from facilities and patients since our last guidance document was issued. Words that are being added are denoted by an underline. Words that are being deleted have a strikeout line through them.

Question: Does the condition of the focal spot have to be measured at all possible magnification values?

Answer: The facility is required to evaluate the focal spot condition only if magnification is clinically used and then at the magnification factor as close to 1.5 as can be achieved with the system

Question: When performing the weekly phantom image test must we monitor kVp and/or mAs?

Answer: No. The only requirements on the weekly phantom image test are that the phantom image achieve at least the minimum phantom scores established by the accreditation body and must be within the action limits established for the 3 optical density requirements. FDA is aware that many facilities are monitoring kVp and/or mAs as part of their weekly phantom QC testing. This is not required. If a facility uses the Full-Auto mode and monitors kVp and/or mAs, it will probably observe that, over time, the Full-Auto mode leads to small variations in the kVp selected by the unit for the phantom exposures. Even small variations in kVp may lead to significant variations in the mAs values obtained. While small variations in kVp are to be expected when using the Full-Auto mode, large variations in kVp (greater than 1 kVp of the value usually obtained) may indicate an equipment problem and should be further evaluated.

Mobile facilities should be aware of the following if they are monitoring mAs as part of their post-move-pre-exam testing. Performing the post-move-pre-exam test in the Full-Auto mode may be ~~inappropriate~~ problematic (due to the variability of kVp and mAs as previously mentioned). In such cases, the facility may: 1. ~~should~~ U~~u~~se the AEC mode to perform the post-move-pre-exam test, even if they use the Full-Auto mode for their patients with the standard breast. Note: The weekly phantom QC test must be performed using the same clinical conditions that the facility uses for its patients with the standard breast.

OR

2. Use the Full-Auto mode and establish baseline mAs values corresponding to the specific kVp values usually encountered during phantom testing. If the mAs value is within 10% of the baseline value for the post exposure kVp value, the unit has passed that portion of the post-move-pre examination test.

Question: What is considered adequate weekly phantom QC monitoring for a facility that has multiple processors and multiple units?

Answer: The answer depends on whether the units and processors are used interchangeably and whether the processors are matched (operating levels for mid density and density difference for all processors are within 0.05 optical density).

If the processors are not matched and the facility is processing clinical films from its multiple units interchangeably through its processors, the facility must conduct the weekly phantom image test for each unit-processor combination. In this example, if a facility has 5 units and 2 processors, a total of 10 phantom images must be performed each week.

If the processors are matched and the facility is processing clinical films from its multiple units interchangeably through its processors, it is acceptable to produce a weekly phantom image from all units and process them through any processor, as long as each processor is tested with a phantom image at least once each week of use. This will reduce the number of phantom images that must be performed. In this example, if a facility has 5 units and 2 processors, a total of 5 phantom images must be performed each week.- Note: At least 1 phantom image must be processed through each processor.

Question: We are a private radiology practice that applied for and became accredited and certified as a mammography facility. We do not own a mammography x-ray unit or employ a radiological technologist qualified to perform mammography. We had applied for accreditation using the x-ray unit and technologist from a certified mobile facility that visits our practice periodically. Do we have to be inspected separately from the mobile facility and who is responsible for correcting any problems found?

Answer: If your facility and the mobile facility are both certified, you are both required to be inspected annually. Your facility and the mobile facility may, under certain circumstances, qualify under our **Inspection Fee Consolidation policy**, which could reduce your inspection fee cost. Regarding who is responsible for correction of problems, both facilities would be responsible for assuring that all aspects of mammography are in compliance prior to performing examinations on patients.

Question: We use FDA's guidance for mobile facilities where we produce a phantom image after a move of the mobile unit and we monitor the mAs. We then process the phantom image later prior to the processing the mammograms. If we move the mobile unit more than once per week, do we also have to produce a weekly phantom image in addition to the phantom produced after each move?

Answer: If you use the mode of operation and/or technique factors used clinically for a standard breast for the phantom images that you produce after each move, you do not have to perform an additional weekly phantom image.

Question: We have an FFDM unit and do not keep hardcopy of our exams (we retain the images electronically). When patients request the release of their exam, we create a hardcopy for them. May we charge the patient for the cost of creating the hardcopy?

Answer: The facility may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests a second copy of the mammogram, the facility may pass the costs of that reproduction on to the patient.

Question: We do not have an FFDM unit at our facility, however, some of our personnel use an FFDM unit at another facility. Are we responsible for maintaining documentation showing that these people have received their initial training in the new mammographic modality?

Answer: No. Only the facility at which these personnel are actually using the FFDM unit is responsible for maintaining the documentation.

Question: How long must we maintain the records of our medical outcomes audit?

Answer: The medical outcomes audit is a quality assurance record and as such must be maintained for at least 2 years. If the facility has obtained actual pathology reports, those should be maintained until the next annual inspection.

Question: When we assign a negative assessment to the mammography report, our reporting system automatically generates a normal lay summary. In rare cases, we have patients that have negative mammograms but for other reasons we want that person to have further work-up or even biopsy. In such cases can we assign a different assessment category to the mammography report so the correct lay summary automatically goes out? Can the medical report and lay summary have recommendations that are not the ones normally associated with a specific assessment category?

Answer: While circumstances as described above should be relatively rare, the decision of which assessment category to assign to a specific mammography report is left up to the interpreting physician. With respect to recommendations, the interpreting physician can make any recommendation he or she believes appropriate.

Question: Are all regulated mammography units in the facility required to be accredited and, if so, what documentation is necessary to establish that this has been done?

Answer: Yes. The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed an equipment evaluation ~~or medical physicist's survey~~ and that the application for accreditation of the unit has been submitted. There are three cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an experimental one installed and used

under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. The requirements for accreditation of these units is dependent on the rules of the facility's accreditation body. Note that under both 1) and 2) the unit still must have passed an equipment evaluation ~~or survey~~ and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.

Question: I qualified as an MQSA radiologic technologist in the past and have been performing mammography for several years. I recently passed the test for the ARRT(M) certificate. Can I claim 24 CEU credit hours for earning this certificate toward my continuing education requirement?

Answer: Yes. You can claim 24 credit hours toward the continuing education requirement for a period of time up to 36 months from the date of obtaining the ARRT(M) certificate.
Discussion:

A facility operating under a six-month provisional certificate (including a provisional reinstatement certificate) may be eligible for a single 90-day extension to its provisional certificate. (A facility operating under a three-year certificate is not eligible for a 90-day extension.)

If the accreditation process is not completed within the six-month provisional period, a facility may apply to FDA, through its accreditation body, for a 90-day extension. To be eligible for a 90-day extension, a facility should have adhered to ~~made a good faith effort to have submitted all necessary images and information in accordance with~~ the accreditation body's schedule in submitting the necessary images and information (i.e., to have completed accreditation in the six month provisional period) and provide evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

To apply for a 90-day extension, a facility should contact its accreditation body. Note: The MQSA Facility Hotline no longer answers questions related to 90-day extensions. Consult with the accreditation body on this issue. ~~submit a request to its accreditation body that includes:~~

~~1. The facility's accreditation body and FDA identification numbers;~~
~~2. An explicit request for a 90-day extension;~~
~~3. A description of circumstances that make the extension necessary, including what the facility is or will do to complete accreditation;~~
~~4. A specific description of how access to mammography will be reduced for the community or population served by the facility;~~
~~5. The name of a contact person, phone number, and fax number.~~

The accreditation body will review the request and forward it, with its recommendation for or against the extension, to the FDA for a decision. FDA ~~should~~ will then review the request and inform the facility and the accreditation body of its decision. ~~In general FDA should be expected to follow the recommendation of the accreditation body.~~

A facility that does not receive a 90-day extension must cease performing mammography when its provisional certificate expires, or when notified by FDA that accreditation has been denied, whichever is first. Additionally, the facility should contact its accreditation body about how to resume the accreditation process.

Question: At the time of the inspection, a mammographic unit is found to not meet one or more of the specific equipment requirements listed in 900.12(b) (3-10). Must the unit immediately be taken out of service?

Answer: No. However, the unit must be replaced, modified or repaired as soon as possible. The facility may continue to use the unit for a limited time, as long as it takes measures to ensure that the failure to comply with the requirement does not result in substandard patient care. The facility is reminded that regardless of what is stated above, the unit must remain in compliance with the requirements listed in 900.12(e) if it is to be used on patients.

Question: Do units with multiple AEC detectors have to have each detector tested individually for AEC reproducibility?

Answer: Where a mammography unit has multiple AEC detectors designed to function independently, each detector must be tested separately (e.g., different AEC detectors for the different size cassette holders or more than one independently selectable AEC detector in a single cassette holder). Where a mammography unit has multiple AEC detectors designed to function as a single unit, the AEC detector unit must be tested. For example, a single detector that can be moved to different positions needs to have the detector tested at only one of those positions. A system with three fixed detectors, each of which can be selected individually, needs to have all three detectors tested. A large field detector that automatically selects its active area needs to be tested only as a single detector.

Question: With the introduction of Full Field Digital Mammography, what constitutes a mammogram, the digital data or the hard copy film?

Answer: There are two sections of the recordkeeping requirement that are affected by the introduction of digital mammography. The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the digital data or hard copy films for the specified periods of time. For purposes of transferring films, the facility must be able to provide the medical institution, physician, health provider, patient or patient's representative, with hard copy films of primary interpretation quality. Facilities may transfer digital images electronically as long as that is acceptable to the recipient (e.g., between two FFDM facilities)

Question: With machines such as the GE 500T and 600T, which do not have a separate mechanism for compression fine adjustment, can tapping the foot pedal for fine adjustment of compression force meet the year 2002 requirement?

Answer: Yes. After receiving input from the National Mammography Quality Assurance Advisory Committee, comments from the public, and performing its own evaluation, FDA has determined that, with proper use, fine compression can be achieved with GE 500T and 600T units by tapping the foot pedal. While FDA recognizes that fine compression can be achieved using these mammography units, the specifics of the compression device require the technologist to pay additional attention during the application of compression. Where this causes clinical problems, facilities may want to consider modifying the compression device to allow for more consistent operator control. Facilities wishing to modify their units may try contacting third-party vendors offering such modifications ~~their GE service representative~~ for more information. Before a facility decides to modify the compression device, the facility should assure itself that the unit meets all the other new requirements (AEC performance, maximum compression force, focal spot condition and radiation output) that go into effect on October 28, 2002.

Changes to Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs

Thickness compensation internal* adjustment
~~Y MP conducts evaluation in person~~
N MP oversight
kVp, mA or time internal* adjustments
~~Y MP conducts evaluation in person~~
N MP oversight
AEC sensor also replaced
Y MP conducts evaluation in person
AEC sensor not replaced
N MP oversight

Discussion:
Accreditation and certification are two separate processes and both are required of mammography facilities under MQSA.
Before a mammography facility can legally perform mammography, it must be certified. To begin the process, it must first contact its selected accreditation body (the ACR or the States of Arkansas, California, Iowa, or Texas if the facility is located in one of those states) and apply for accreditation. When the application has been accepted for review, the accreditation body will notify FDA, which will then send the facility a six-month provisional certificate. The facility must collect the clinical images and other data that will be needed for completion of the accreditation process and respond to all requirements of the accreditation body in a timely manner. If the facility has not completed the accreditation process prior to the expiration of the provisional certificate, it must cease performing

mammography. A facility that has adhered to the accreditation body process timeframes ~~diligently pursued its accreditation~~ may qualify for a 90-day extension of the provisional certificate.

A new facility whose application has been accepted by an accreditation body should receive its FDA certificate within 7 to 10 days after FDA has been notified. Prior to that, the facility will receive an Interim Notice within 2 to 3 business days. A facility that has not received its Interim Notice after 3 business days should notify the Mammography Quality Assurance Program by fax at 1-410-290-6351. The facility should prominently display this interim notice until it receives its FDA Mammography Facility Certificate.

Certification is valid for three years and can be renewed as long as the facility remains properly accredited and successfully demonstrates during its annual inspections that it continues to meet the MQSA quality standards.
Interested parties may find out which mammography facilities are certified as follows:

· The FDA MQSA Website (http://www.fda.gov/cdrh/mammography) has a link to "Listing of FDA Certified Mammography Facilities" that lists facilities by selected state or by specified three-digit zipcode area. This information is updated weekly.

· The National Cancer Institute (NCI) has information regarding breast cancer and mammography, including a list of FDA-certified mammography facilities in a caller's area through their hotline: 1-800-4-CANCER (1-800-422-6237).

· A complete listing of all certified facilities may be ordered from the National Technical Information Service (NTIS) for a fee. The information is updated quarterly and is provided on 3-1/2" diskettes in ASCII format. Call 1-800-363-2068 or 1-703-605-6060 to order either a single disk (SUB 5286/Code D01) or a one-year subscription (SUB-5386).

Question 1: Under what circumstances may FDA issue Interim Notices?

Facilities may call the FDA hotline to request assistance when they have not received a certificate or have other questions pertaining to certification, or they may contact their accreditation body with a similar request, and the accreditation body may contact FDA to request issuance of an interim notice. ~~In all cases t~~The following criteria ~~should~~ will be used by FDA to determine whether an interim notice should be issued to a facility.
FDA may issue an Interim Notice to a mammography facility under the following two sets of circumstances:

1) CERTIFICATE DELAY: There may be a delay in issuing or delivering a certificate to a facility that has met the requirements for a provisional or provisional reinstatement certificate, or has completed accreditation or reaccreditation and the facility's certificate has or is about to expire.

2) REACCREDITATION OR ACCREDITATION COMPLETION DELAY: There may be a delay in completing reaccreditation or accreditation beyond the expiration date of a facility's certificate for various reasons such as delay in completion of clinical image review. For a facility to be eligible to receive an interim notice, all of the following criteria should be met:

a) the facility has an expired or expiring three year FDA Mammography Facility Certificate, or the facility has an expired or expiring provisional certificate and accreditation is imminent;

b) the reaccrediting facility has applied for reaccreditation in a timely manner, i.e., at least six months prior to the expiration date of ~~the~~ its certificate. Facilities receive ample notice from their AB's ~~seven to nine~~ several months prior to expiration of their accreditation, that they should apply for reaccreditation. FDA considers six months prior to certificate expiration to be a minimum time frame that is adequate for reaccreditation;

c) the facility has adhered to the accreditation body process timeframes~~shown a good faith effort in completing the accreditation/reaccreditation process in a timely manner~~, i.e., submitted its clinical images and other information in time to complete normal review within the six-month accreditation/reaccreditation window; and

d) the delay should not otherwise be due to inappropriate facility activities.

Question 2: What should a facility do if its certificate expires before it is accredited or reaccredited?

If a facility's certificate expires before it has been accredited or reaccredited, it must immediately stop performing mammography or it may be subject to civil monies penalties of up to $10,000 per examination. Before the certificate expires, a facility should contact its accreditation body to discuss its options for continuing to perform mammography~~see if it meets the requirements for an Interim Notice or 90-day extension~~.

Question: ~~A~~ Before a facility ceases operations and closes its doors,~~.~~ w~~W~~hat actions should it take to avoid future MQSA problems and how should it deal with retention of mammographic medical records?

Answer: ~~When~~ Before a facility ceases operations and closes its doors, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;

2. The MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate;

3. Notify its State radiation control program;

4. Arrange transfer of each patient's medical record (original mammography films and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less that 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. Facilities should check with State or local agencies to determine if their requirements are more stringent.

If the option in number 4 is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films to the appropriate entity when requested. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Due to the fact that some facilities have not followed the above recommendations, FDA has been receiving inquiries from patients complaining that their mammography facility has closed, that they were not informed, that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that the facility notify us of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:
FDA/CDRH/OHIP/DMQRP
Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

Question: What criteria will FDA use to determine that facilities meet the MQSA requirements for infection control?

Answer: To meet the MQSA requirements for infection control, the facility must:

1. provide written documentation that describes the infection control procedures used by the facility. If reference material is cited in the facility's description of its procedures, the facility must have a copy of the referenced material. The procedures used by the facility must comply with applicable Federal, State and local regulations as well as manufacturer's recommendations.
2. have documentation (e.g., logs or charts) indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials. In those cases where there has not been an episode of contamination since the last inspection, the facility should make that clear to the inspector.